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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/680,560 | 10/06/2003 | Tuoc Tan Nguyen | 816020-100044-US | 4130 |
| 34026 | 7590 | 10/05/2005 | EXAMINER | |
| JONES DAY 555 SOUTH FLOWER STREET FIFTIETH FLOOR LOS ANGELES, CA 90071 | | | MILLER, CHERYL L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/680,560 | NGUYEN ET AL. |
| | Examiner | Art Unit |
| | Cheryl Miller | 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 July 2005.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3,4,6 and 7 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3,4,6 and 7 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 5/4/05.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: attachment 1, 2.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1 and 3-7 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claim 1 is objected to because of the following informalities: The claim recites, "wherein said flexible vertical posts further comprise single diamond-shaped element". As claimed, it seems that the group of posts comprise one diamond element. However, the drawings show, one element per post, not group of posts. This is a possible new matter issue if not corrected in the next response. It is suggested to change the above to recite, "wherein each flexible vertical post further comprise a single diamond-shaped element". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. (US 6,425,916 B1, cited in IDS) in view of Myers et al. (US 2002/0052651 A1, cited previously). Referring to claim 1, Garrison discloses a valve assembly (see fig.5, 6, 9) comprising a replacement valve (6 or 38, seen in fig.10) having an inflow annulus (41; bottom of fig.), an outflow annulus (top of fig), and a plurality of leaflets (39) in between the inflow and

outflow annulus (fig.10, 11), and an expandable and collapsible anchoring structure (8; fig.7-9) dimensioned to extend longitudinally from an inflow attachment location to an outflow attachment location, the anchoring structure (8) comprising a singled flared inflow rim (18; there is only one inflow rim) and only three flexible vertical posts (posts extending from 18, seen in fig.7-9, particularly in fig.7; only three are shown) extending from the inflow rim (18) in a direction toward the outflow annulus of the valve (6) wherein the vertical posts further comprise a single diamond shaped (opening 14; there only being *one* opening 14 associated with each vertical post, see attachment 1) element having no direct contact with the replacement valve (there is no contact, since the anchoring structure 8 is flared away from the valve 6, and the valve is only in contact at protrusions 36, which extend through openings 14, below the diamonds). Garrison however, discloses the inflow and outflow annulus to be straight rather than scalloped. Myers teaches in the same field of valve assemblies, the use of scalloped inflow and outflow annuluses on replacement valves like the one of Garrison (see figures 8, 9, 17, 28, and 29), as an improvement to straight annuluses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve [0088-0090]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Garrisons heart valve prosthesis, with Myers teaching of scalloping annuluses of valve prostheses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve.

Referring to claims 3, 4, 6, and 7, see figures 5-10, 25, and 26 and respective portions of the specification.

Claims 1, 3, 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seguin et al. (US 2004/0093060 A1, cited previously) in view of Myers et al. (US 2002/0052651 A1, cited previously). Referring to claim 1, Seguin discloses a valve assembly (see fig.19, 21, and 22) comprising a replacement valve (10 or 102; see fig.4, 14, and 17) having an inflow annulus, an outflow annulus, and a plurality of leaflets in between the inflow and outflow annulus (fig.4, 14, 17 and respective portions of the specification), and an expandable and collapsible anchoring structure (stent in fig.19, 21, and 22) dimensioned to extend longitudinally from an inflow attachment location to an outflow attachment location, the anchoring structure comprising a singled flared inflow rim (104+105 in figs) and only three flexible vertical posts (105a+105b+103; see attachment 2) extending from the inflow rim (104+105) in a direction toward the outflow annulus of the valve wherein the vertical posts (105a+105b+103) further comprise a single diamond shaped (portion of 103 coinciding with 105) element having no direct contact with the replacement valve (diamond is located below where the valve is placed, therefore, no contact). Seguin however, discloses the inflow and outflow annulus to be straight rather than scalloped. Myers teaches in the same field of valve assemblies, the use of scalloped inflow and outflow annuluses on replacement valves like the one of Seguin's (see figures 8, 9, 17, 28, and 29), as an improvement to straight annuluses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve [0088-0090]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Seguin's heart valve prosthesis, with Myers teaching of scalloping annuluses of valve prostheses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve.

Referring to claims 3, 4, 6, and 7, see figures 19, 21, and 22, and respective portions of the specification.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER

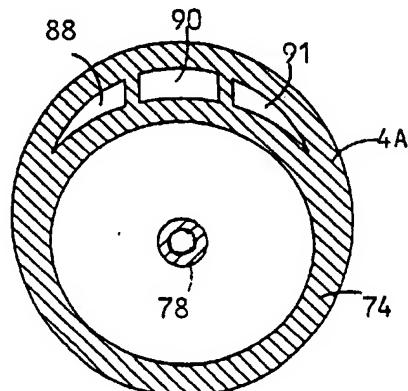
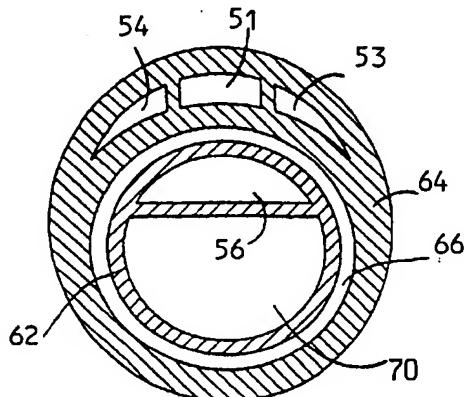
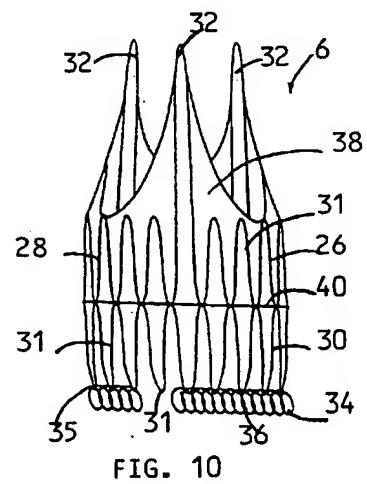
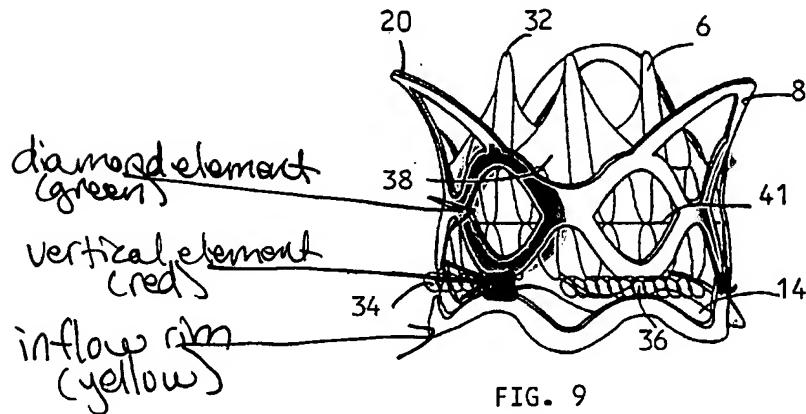
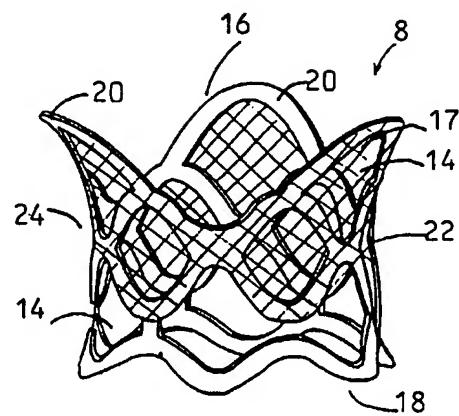
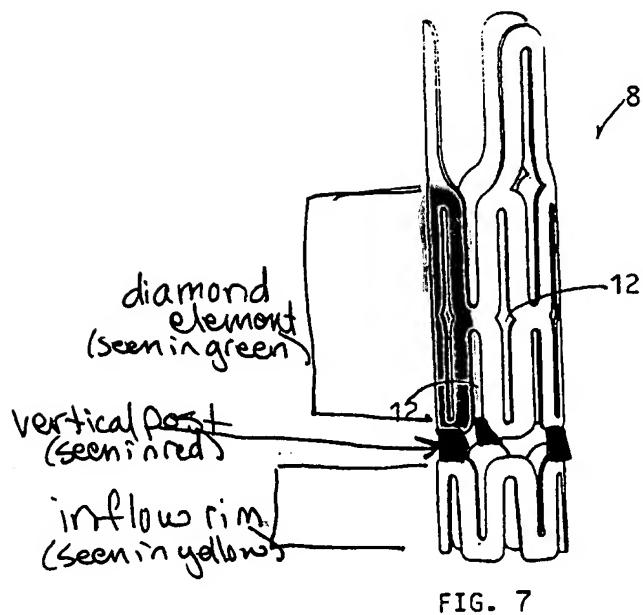
Attachment #1 (marked up)

U.S. Patent

Jul. 30, 2002

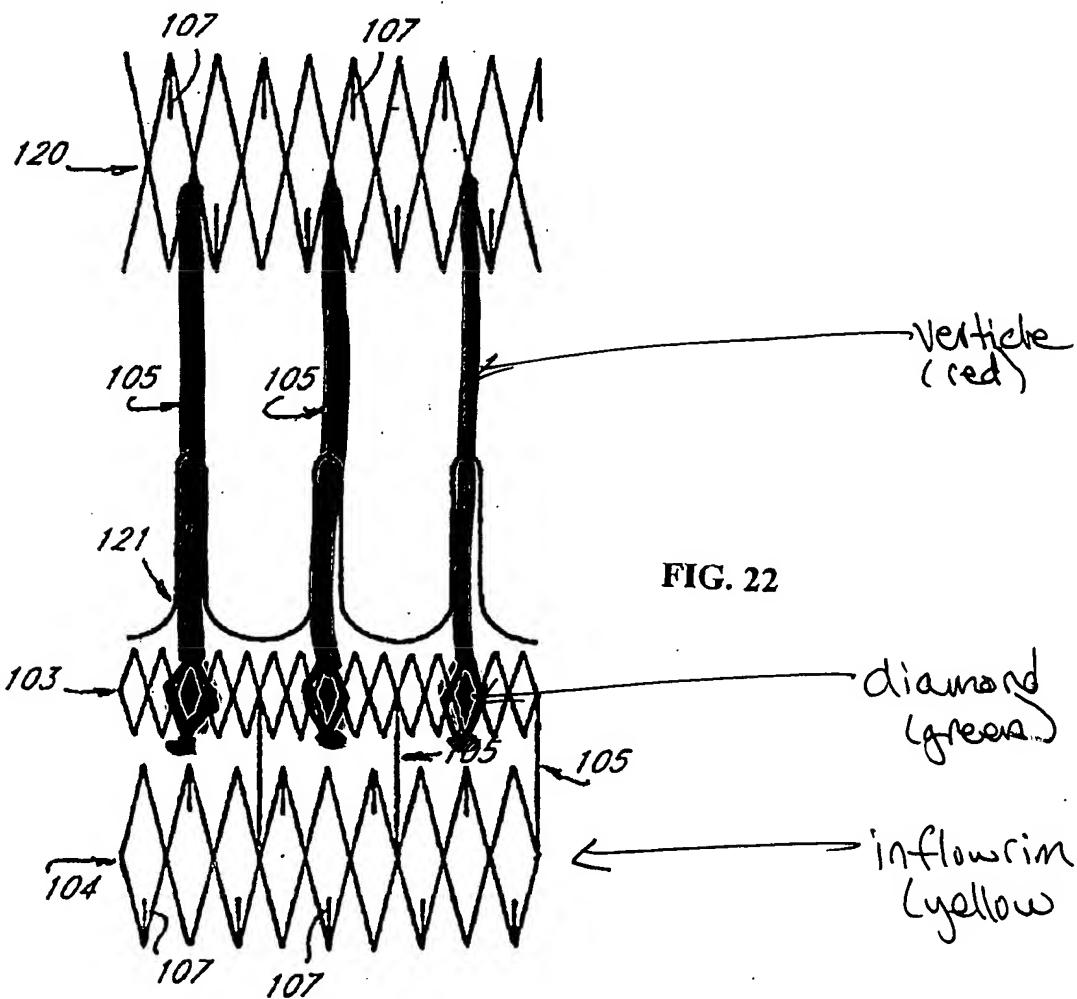
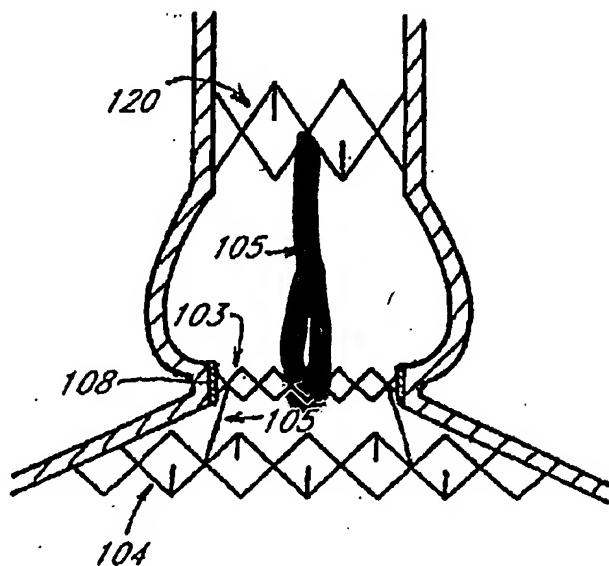
Sheet 6 of 23

US 6,425,916 B1



Attachment #2 cont. (marked up)

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Attachment #2 (marked up)

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FIG. 19

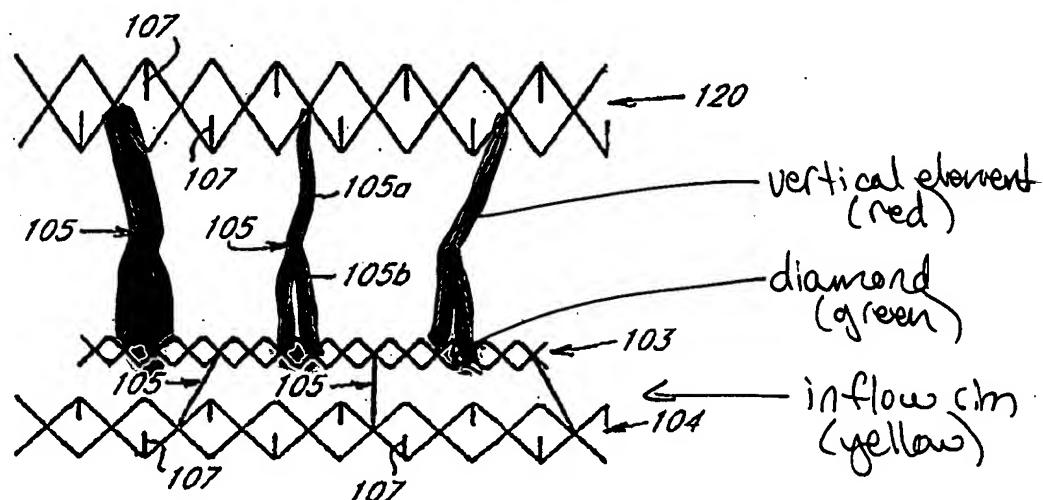


FIG. 20

